NATIONAL STONE, SAND & GRAVEL ASSOCIATION







Natural building blocks for quality of life

September 30, 2008

NIOSH Docket Office NIOSH Mailstop C-34 Robert A. Taft Lab Mail Stop C-34 4676 Columbia Parkway Cincinnati, Ohio 45226

RE: "Asbestos Fibers and Other Elongated Mineral Particles: State of the Science and Roadmap for Research" NIOSH Docket Number NIOSH 099-A

As requested by the National Institute for Occupational Safety and Health (NIOSH), the National Stone, Sand and Gravel Association (NSSGA) is pleased to provide these comments on the above captioned document.

NSSGA, based near the nation's capital, is the world's largest mining association by product volume. Its member companies represent more than 90 percent of the crushed stone and 70 percent of the sand and gravel produced annually in the U.S. and approximately 120,000 working men and women in the aggregates industry. The vast majority of the products from our industry are utilized in public infrastructure projects.

The NSSGA has had a long history of working cooperatively with NIOSH on many occupational health issues over the years and it looks forward to active involvement on this very important issue to our many miners, our industry, its many customers and the nation.

Please see the enclosed document NSSGA Review of the NIOSH Asbestos Fibers and Other Elongated Mineral Particles: State of the Science and Roadmap for Research June 2008 for NSSGA's specific comments on the Roadmap.

In addition, NSSGA has included, to be added to the docket, a number of papers which have bearing on this important issue.

Thank you for the opportunity to comment on this important issue.

Sincerely,

William C. Ford, P.E. Senior Vice President

Attachments

NSSGA Review of the NIOSH Asbestos Fibers and Other Elongated Mineral Particles: State of the Science and Roadmap for Research June 2008

Executive Summary (pp vl - x)

vi 2nd Paragraph: "It remains uncertain whether other thoracic-sized EMPs, especially those EMPs with mineralogical compositions similar to the asbestiform minerals, warrant similar health concern."

The Occupational Safety and Health Administration, Mine Safety and Health Administration and the Consumer Products Safety Commission have examined the science and concluded that the nonasbestiform mineral habits of the asbestos minerals do not present an asbestos-like health concern. Based on the current science and supported by the findings of the agencies listed above, NSSGA believes that there is certainty with respect to the health effects associated with exposure non-asbestiform EMPs. With that said, we are pleased that NIOSH is prepared to re-examine their long-standing position on this issue.

vi 3rd Paragraph: "In 1990, NIOSH revised its recommendation concerning occupational exposure to airborne asbestos fibers. At issue were concerns about potential health risks associated with worker exposures to EMPs with mineralogical compositions similar to those of the asbestos minerals and the inability of the analytical method routinely used for airborne fibers (i.e. phase contrast microscopy (PCM)) to differentiate between these other EMPs and fibers form the asbestos minerals."

NIOSH does not identify which worker exposures (specific studies) gave it concern about potential health risks to nonasbestiform minerals. The inability to differentiate EMPs from asbestos should not be a reason for treating nonasbestiform minerals as if they were asbestos. The development of more asbestos-specific analytical methods should be a focus of the proposed research.

vii 1st Paragraph: "NIOSH also wishes to minimize any potential future confusion by no longer referring to particles from the nonasbestiform analogs of the asbestos minerals as 'asbestos fibers'. In a clarified REL presented in this Roadmap, NIOSH avoids referring to particles from such nonasbestiform minerals as 'asbestos fibers' and clarifies that particles meeting the specified dimensional criteria remain countable under the REL even if they are derived from nonasbestiform minerals."

It appears that NIOSH agrees that nonasbestiform mineral analogs of the asbestos minerals are not asbestos but it also appears from the statement above that the distinction will not be deemed relevant for the purposes of determining RELs. The distinction between asbestiform and non-asbestiform particles as it

relates to their potential to cause disease is a key issue in this research and should not be presumed until the research is complete.

vii-viii 2nd Paragraph: "More sensitive analytical methods are currently available, but these methods will require standardization before they can be recommended for routine analysis. In addition, any substantive change in analytical techniques used to evaluate samples and/or the criteria for determining exposure concentrations will necessitate a reassessment of current risk estimates derived from fiber concentrations based on PCM."

This effort needs to be a research priority for NIOSH since the current method is counting non-asbestos as asbestos which misdirects resources away from true asbestos exposures and will undermine the protection of worker health.

viii 2nd Paragraph: "...results from epidemiological studies do not provide entirely clear answers regarding potential toxicity of EMPs from the nonasbestiform analogs of the asbestos minerals. Due to various study limitations, NIOSH has viewed findings from relevant epidemiological studies as providing inconclusive, as opposed to either positive or negative, evidence regarding health hazards associated with exposures to EMPs from nonasbestiform amphiboles."

With respect to mesothelioma, the Homestake Goldmine and New York talc cohorts are extremely strong negative studies indicating an absence of this hallmark asbestos disease even with considerable exposure to amphiboles (cummingtonite-grunerite and tremolite respectively). The published, peer-reviewed taconite studies do not have sufficient latency for mesothelioma to be seen and so are less relevant with respect to mesothelioma.

The Homestake Goldmine EMP exposure was not inconsequential. The incidence of silicosis and silicotuberculosis deaths and disease in the cohort demonstrates that exposures to the silica-amphibole rich ore deposit was significant for many decades yet there is an absence of asbestos-related disease. A critique of the original NIOSH mortality study on Homestake is attached and it clearly shows the exposures to Homestake miners in the early 1900's through the 1970's were significant.

The tremolite cleavage fragment exposure of the New York talc workers was also considerable. This level of exposure is evident from the non-malignant dust diseases found in mortality studies of these workers. This deposit contains up to 60% tremolite and yet there are no asbestos-related diseases in the miners and millers. A complete, peer-reviewed published article on the epidemiological differences between asbestos and cleavage fragments by Drs. Graham Gibbs and John Gamble is included in these comments to NIOSH. Based on the studies referenced, NSSGA does not understand the basis upon which NIOSH considers this science inconclusive and would welcome additional dialogue on this issue.

Page 12 1.5 Components of the NIOSH Recommendation for Asbestos

NIOSH appears to use an arbitrary set of dimensional counting criteria as a <u>definition</u> of asbestos but these dimensions do not define asbestos and do not relate to health effects. The NSSGA respectfully requests NIOSH (and NAS) to research the origins of these counting criteria (Walton 1982) to verify that they do not define asbestos and more importantly do not relate to health risk. Misusing the counting criteria as a definition of asbestos means that all common antigorite, riebeckite, cummingtonite-grunerite, tremolite, actinolite and anthophyllite will be considered to be asbestos unless their rock fragments are less than 5 microns long or have an aspect ratio that is less than 3. This is not consistent with mineralogical or health risk based science and will be less protective of human health because resources will be diverted to address exposures that do not cause disease.

Page 13 1.5.1 Minerals Covered by the NIOSH REL

NIOSH specifically includes the nonasbestiform analogs of the asbestiform minerals (the serpentine minerals antigorite and lizardite, and the amphibole minerals contained in the cummingtonite-grunerite mineral series, the tremolite-ferroactinolite mineral series and the glaucophane-riebeckite mineral series) in the definition of asbestos without any cellular, animal or epidemiological studies cited as support for this broadening of the asbestos definition. As we have done in the past, NSSGA respectfully requests any reports or articles in support of the broader definition so that we can better understand NIOSH's postion on this issue. The following is an excerpt from the OSHA 1990 public hearing:

Question: "Now let me turn to the NIOSH definition of minerals to be included as asbestos in your testimony. This definition includes new minerals such as antigorite which have not before been proposed for regulation; is that correct?"

Richard Lemen [formerly] of NIOSH "Yes"

Question: "And am I correct in thinking that NIOSH is the only government agency that has made this proposal?" [And it still is].

Richard Lemen: "As far as we know. I can't be certain of that."

Question: "Would you agree that for antigorite, one of these minerals, that there are no studies showing a positive cancer effect similar to asbestos?"

Richard Lemen: "That is true. And the reason that they are included is because of cleavage fragments."

Question: "Let me ask you as to a number of other of these. With respect to cummingtonite-grunerite, and riebeckite, would you also agree that there similarly are no studies showing a positive cancer effect similar to asbestos?"

Richard Lemen: "This is true."

Page 14 1.5.1.1 Chrysotile

This discussion regarding chrysotile focuses more on the differences in potency between amphiboles and chrysotile and does not address the differences in asbestos related mortality between chrysotile miners and chrysotile textile

workers. In the Quebec chrysotile mines, the primary mineral present is not chrysotile (~5%) but rather antigorite and lizardite (90-95%). In the early studies of exposure to chrysotile miners, the exposure was measured in million particles per cubic meter (mppcf) of air using an impinger. Most of those particles would have been antigorite not chrysotile. In the conversion of mppcf to fibers per cubic centimeter, this mineralogical fact was not considered therefore much of the antigorite/lizardite was incorrectly counted as asbestos which inflated the "asbestos" dose and resulted in a faulty dose-response relationship for the chrysotile miners. See attached publication: Mineralogy and size of airborne chrysotile and rock fragments: Ramifications of using the NIOSH 7400 method. Wylie and Bailey 1992.

The case described above calls into question NIOSH's position that antigorite and lizardite should be regulated as if they were asbestos. This position is not consistent with the fact that very large exposures to antigorite and lizardite "fibers" in the chrysotile miners (much higher than asbestos exposures to the textile workers) resulted in significantly lower asbestos-related mortality.

Page 15 1.5.1.2 Amphibole Asbestos and Other Fibrous Minerals

The NSSGA supports the inclusion of all asbestiform amphiboles and asbestiform erionite in any asbestos regulation as long as the term asbestiform is applied in its mineralogical definition:

Asbestiform mineral populations generally have the following characteristics when viewed by light microscopy:

- 1. Many particles with aspect ratios ranging from 20:1 to 100:1 or higher for particles > 5 microns in length.
- 2. Very thin fibrils generally ≤ 0.5 microns in width
- 3. In addition to the mandatory fibrillar crystal growth, two or more of the following attributes:
 - a. Parallel fibers occurring in bundles
 - b. Fibers displaying splayed ends
 - c. Matted masses of individual fibers
 - d. Fibers showing curvature

The above definition of what asbestiform is mineralogically is found in the 1993 EPA asbestos bulk analysis method and the NIST certificate in its asbestos standards.

1.5.1.3.1 Rationale for NIOSH Policy

The NSSGA does not understand NIOSH's rationale for its position of equating common rock cleavage fragments, based on counting criteria dimensions that do not relate to health risk or mineralogy, to asbestos in light of the overwhelming evidence that there are substantial health differences between these mineral habits or forms. NSSGA is not aware of any science or data that lends support to NIOSH's position and we offer the following in support of our position that

exposure to non-asbestiform cleavage fragments or EMP's does not cause the same health effects as exposure to asbestos:

- 1. Ten epidemiological studies of Homestake gold, New York talc and Minnesota taconite miners and millers that had significant nonasbestiform amphibole exposures meeting the counting criteria of a fiber yet do not show an asbestos-related disease or dose-response relationship. In addition, the chrysotile miners, exposed to significant levels of antigorite and lizardite cleavage fragments (as well as chrysotile asbestos) do not show the same exposure response as other chrysotile exposed cohorts. Since NIOSH's position is that antigorite and lizardite are equally potent to asbestos if the rock fragments fit the counting criteria, one would expect to see this reflected in the published mortality studies of chrysotile miners and millers.
- 2. Six animal studies where eight samples of nonasbestiform tremolite and one sample of nonasbestiform actinolite were either injected or implanted in the pleura or instilled in the trachea in either rats or hamsters without causing tumors. This is in contrast to studies where asbestiform tremolite and asbestiform ferroactinolite demonstrate the potent ability to generate tumors in either rats or hamsters by any route of administration. Samples that were mixed asbestiform and nonasbestiform also demonstrated the ability to cause tumors. A complete, peer reviewed literature review of the animal studies relevant to this issue by John Addison and Dr. Eugene McConnell is enclosed with these comments to NIOSH.
- 3. There are fourteen *in vitro* studies or reviews of the science that contrast the toxicological outcome between the asbestiform and nonasbestiform habits of the same minerals. Most of these studies involve chrysotile and its nonasbestiform counterpart, antigorite, crocidolite and its nonasbestiform counterpart, riebeckite and amosite and its nonasbestiform counterpart, cummingtonite-grunerite. These studies were conducted in a variety of species and cell types including hamster tracheal explants, hamster tracheal epithelial cells, rat lung epithelial cells, rat and hamster alveolar macrophages, rat pleural mesothelial cells, sheep red blood cells, and Chinese hamster ovary cells. All of these studies clearly show a marked toxicological difference between the nonasbestiform and asbestiform habits of the same minerals. A complete, peer-reviewed published article covering the *in vitro* studies relevant to this issue by Dr. Brooke Mossman is enclosed with these comments to NIOSH.

These cellular, animal and human studies are very consistent in what they reveal — asbestos and their nonasbestiform analogs are not equal in potency and the findings do not support NIOSH's position on cleavage fragments.

Page 24 Lines 24 - 37

We do not concur with NIOSH in relating a slight increase in lung cancer to exposures at the Homestake mine when there is no exposure-response

relationship observed and smoking is not taken into account. NIOSH appears to further understate the importance of the Homestake studies by implying that the dust exposure did not contain enough EMPs to see a response. In a critique of the first NIOSH study of Homestake (enclosed) it is reported that NIOSH, citing a 1974 Mining Enforcement and Safety Administration (MESA) fiber survey, states that the average > 5 micron long fiber concentration was found to be 0.25 fibers/cc with the highest value at 2.8 f/cc. These 1974 data do not represent the historical exposure levels. Homestake mine data from 1937 – 1951 indicate that dust exposures (and concurrent EMP exposures) were 8 times higher than those in 1974 when MESA did its fiber survey. Homestake mine data on ventilation in the mine show that the dust exposures from 1924-1932 were approximately 16 times higher than what was present in 1974 and those for the period 1916 -1923 were 20 times higher. This is not an insignificant exposure to dust as the silicosis incidence in Homestake studies also indicate. NSSGA believes that the Homestake studies are important and the results should be carefully considered by NIOSH moving forward.

Page 27 Lines 18-20

What is the scientific basis for the following statement in the NIOSH Roadmap?:

"However, dust exposures are a very poor surrogate of exposure to nonasbestiform EMPs in these settings."

In a 2005 investigative report by MSHA on a taconite mine (enclosed), the following statement is made following analysis of this relationship:

"These regressions indicate that the specific relationship between respirable dust and fiber concentration varies depending on the material being supplied to the plant. However, regardless of the material, the fiber concentration increased as the dust concentration increased."

Pages 47 – 54 Studies comparing EMPs from asbestiform versus nonasbestiform habit of an amphibole

Page 47 Lines 33-41

It is unclear if the "fibers" with minimum aspect ratio of 3:1 were also longer than 5 microns or were they of all lengths. Not knowing the length criteria makes interpretation of the percentages in the different aspect ratio categories difficult.

Page 48 Lines 2 - 6

In the Wagner paper there were 47 animals tested with the asbestiform tremolite and 14 mesothelioma tumors were reported for an incidence rate of

30%. The Roadmap says 37 were tested. The authors report that the tumor rate would probably have been higher but the testing period was shortened due to mortality due to infection. The dimensions used in Wagner's paper for "fibers" are not included in the paper and therefore it is difficult to know what constituted a dose of fibers from his Table I.

Page 49 Lines 1 - 19

The Roadmap cites several animal studies where cleavage fragments of tremolite were used in rats or hamsters. These studies, when contrasted against the results from asbestiform tremolite, tell a great deal about the differences between the potency of the two different mineral habits. The four studies that demonstrate these divergent results are those conducted by Merle Stanton, John Addison and J.M.G. Davis, J. C. Wagner and William Smith. There are twelve tremolite samples used across these four studies. When one looks at the dimensions of the federal fibers (longer than 5 microns, minimum aspect ratio of 3:1, and at least 0.25 micron wide) in each of these samples, it is consistently observed that the higher proportion of tremolite federal fibers with widths less than 0.5 um, the greater the incidence of tumors. Conversely, the higher the proportion of tremolite federal fibers with widths greater than 1.0 um, the lower the incidence of tumors. In fact, where tremolite federal fibers are predominately greater than 1.0 um in width, no tumors or insignificant tumors (5-12%) are observed. This relationship for these four studies are graphically depicted (Figures 1-4) in Appendix 1 attached to these comments.

Figures 5-8 in Appendix 1 clearly demonstrate the biological "inverse" relationship with the composite plots by particle width. Figures 7 and 8 demonstrate the traditional toxicological dose-response association.

It can be concluded from this comparison that tremolite federal fibers have different carcinogenic effects (ranging from strong to none) depending upon particle width. Specifically, this comparison shows that tremolite federal fiber dust populations with widths predominately less than 0.5 um, but almost exclusively less than 1.0 um, are not biologically the same compared to tremolite federal fiber populations with widths predominately greater than 1.0 um, but almost exclusively greater than 0.5 um in width (see Table 1 in Appendix1).

Beyond the dimensional distribution of particles in a single sample, the Roadmap does recognize the importance of exposure dose. Accurately determining dose in any particulate exposure is complicated by the fact that particles vary widely in weight relative to length, width and particle type. Weight alone is therefore not a good predictor of particle dosage. A 10 mg dose of narrow fibers, for example, will obviously contain far more particles than a 10 mg dose of broad particles (lengths being relatively similar). Bearing in mind the tremolite federal fiber question, the dose issue for some of these same animal studies can be examined from published particle counts expressed in both weight and dimension. This information was available only

in the Stanton and Addison/Davis studies and is presented in Table 2 in Appendix1.

Figure 9 in Appendix 1 shows the number of tremolite federal fibers per mg in Stanton's Tremolite 1, 2, and Talc 6 (tremolitic talc) samples. For tremolite federal fibers greater 1 um in width, there were approximately 2.5 times **more** in Talc 6 (no tumors) than in Tremolite 1 (100% tumors). Talc 6 had 3.7 times **more** than Stanton's Tremolite 2 sample which also had 100% tumors. Conversely, the number of tremolite federal fibers \leq 1.0 um and \leq 0.5 um in width in Tremolite 1 and 2 vastly outnumbered those in Talc 6.

Figure 10 shows the number of tremolite federal fibers per mg for all six of the Addison/Davis samples. The California, Korean and Dornie tremolite samples provide the most important dose information relative to carcinogenic response. The Dornie sample (which authors suggest "is probably harmless to human beings") exceeds both the Korean and California tremolites (97% + tumors with short survival time) in the number of tremolite federal fibers with a width greater than 1.0 um. The actual number of tremolite federal fibers per mg was 133×10^5 (Dornie) versus 106×10^5 (Korean) and 81×10^5 (California). All samples which produced prolific tumors and short animal survival time contained massive numbers of tremolite federal fibers with widths below 1.0 um.

Figures 11 and 12 clearly demonstrate a strong, unmistakable, dose-response relationship with the number of tremolite federal fibers per mg of test material having diameters less than 1.0 or 0.5 micron. Figure 13 shows that this classic toxicological response does not hold for tremolite federal fibers greater than 1.0 um in diameter. In Figure 13 there is **no** association between the number of tremolite federal fibers greater than 1.0 micron in diameter and increased tumor incidence. This fact clearly dispels the position that a "continuum" of carcinogenic response exists for all sizes of tremolite federal fibers.

It can be concluded from this comparison that because <u>more</u> tremolite federal fibers with a width greater than 1.0 um existed in samples which produced no clear carcinogenic effect, <u>similarly sized</u> particles in any other sample cannot reasonably be linked to tumor induction. In a mixed dust exposure it is not logical to indict those portions of the exposure shown to be of lesser risk when tested separately at a higher dose. When this observation is coupled with the proportional particle dimension comparisons, the justification for regulating <u>all</u> tremolite federal fibers in the same way vanishes.

In addition to the animal studies referenced above, there is a considerable body of literature which addresses both dose and particle dimension. This body of literature provides additional insight into the issue of cleavage fragments and asbestos carcinogenicity. In a series of experiments involving asbestos and other mineral and man-made fibers, Fredrick Pott, demonstrated that "very low doses between 0.05 and 0.5 mg asbestos led to tumor incidences of about 20 to 80% (Pott, 1987). The incidence of tumors in this case was roughly proportional to the dose. This finding strongly suggests

that in large doses of dust injected or implanted in animals, small amounts of asbestos in an otherwise non-asbestos dust is sufficient to cause tumors. It is likely that the late tumors observed in the Addison/Davis Italian and Dornie samples were related to an asbestos subpopulation present in these samples. The Dornie sample had 10% tremolite federal fibers that were less than or equal to 0.5 um in width. Federal fibers with widths \leq 0.5 um are certainly not characteristic of tremolite cleavage fragments. Also, it must be noted that Pott's findings indicate that the use of average or mean dimension in describing a dust sample population can be seriously misleading.

Although more than mere dimension is likely involved in particle pathogenicity, certain dimensional characteristics stressed by Dr. Stanton are relevant to the issue of cleavage fragments and asbestos. Beyond the dimensional comparison of Stanton's Tremolite and Talc 6 samples, it is possible to contrast the number of Stanton's critically sized fibers he felt was most associated with tumor induction (≤ 0.25 um in width and > 8.0 um in length) to the occurrence of such fibers in the animal studies referenced above. Figure 14 in Appendix 1 compares the percent of tremolite federal fibers in each of the animal study samples to Stanton's "critical dimension" particles. Samples which contained Stanton's "critical dimension" particles were all associated with prolific tumor induction while those with no Stanton critical dimension tremolite fibers were not.

Stanton's work was reanalyzed by Dr. Gary Oehlert whose work was published in Environmental Research in 1991 (copy of publication is enclosed with these comments to NIOSH). Basically Dr. Oehlert's analysis reconfirms that the number of critically dimension particles is the primary predictor of tumor incidence. However, fitting separate intercepts and/or slopes to each mineral type resulted in substantial significant improvement of fit indicating the importance of mineral type. This contrast with the "Stanton Hypothesis" which states that dimensional properties alone determine carcinogenicity.

Another effort which directly addresses particle dimension and carcinogenicity can be seen in the work of Morton Lippmann. In formulating his conclusions relative to particle dimension and biological effect, Dr. Lippmann addressed the work of Timbrell, Davis, Wagner, Pott, Stanton, Harrington, Holt, Pooley and others. Dr. Lippmann concludes from his dimensional review that "the risk of lung cancer is associated with long fibers, especially those with diameters between 0.3 and 0.8 um, and with a substantial number of fibers > 10 um in length..." In regard to mesothelioma, Lippmann states "that the critical fibers for mesothelioma induction have lengths between 5 and 10 um." In terms of diameters, Lippmann concludes mesothelioma risk "has been related to fibers with diameters < 0.1 um."

Table 3 in Appendix 1 contrasts the percent federal fibers in the animal study samples to Dr. Lippmann's "carcinogenic" size parameters. This comparison demonstrates a reasonable correlation between these size parameters and the carcinogenic effect observed in these studies. Similar to the Stanton critical dimension comparison, tumor incidence is generally proportional to the concentration of fibers which satisfy Lippmann's parameters. Again, as dust

exposures contain more particles with widths < 1.0 um and lengths greater than 5 um, more tumors are observed.

The purpose of the above analysis was to test whether or not the existing federal fiber definition is overly broad and includes tremolite particles which do not pose the same health risk as other tremolite particles or "fibers" covered under the same "definition" or counting criteria NIOSH uses for asbestos. In this review, there is indeed a clear difference in biological effect with differently sized tremolite federal fibers.

Most everyone would agree that the very thin, long dimensions of asbestos tremolite fibers are carcinogenic in animals and that **this** federal fiber component in a mixed dust exposure can cause tumor formation. It is also known that in animal injection/implantation studies it does not take many of these fibers to yield tumors. The existing literature in the field clearly demonstrates that federal fibers with a width greater than **at least** 1 um cannot reasonably be associated with a carcinogenic effect.

Remarkably, the strongest evidence against a carcinogenic association for common cleavage fragments may well be the very animal studies that NIOSH cites as the reason for treating them as if they were asbestos. It has been shown that on a simple, straightforward dimensional basis alone, these animal studies do tell a great deal about "appropriately sized" fibers and the inadequacy of the simplistic federal fiber definition advocated by NIOSH relative to carcinogenic risk.

Page 54 1.7 Analytical Methods

We have enclosed with these comments two documents that pertain to the analytical challenge with this issue. The first is an MSHA method by R. L. Clark that was published in 1982 from the proceedings of the NBS/EPA asbestos workshop. The second is a recent published paper titled Differentiating Amphibole Asbestos from Non-asbestos in a Complex Mineral Environment by D Van Orden, K. Allison and RJ Lee. These two publications show that analyzing for asbestos is a straight forward procedure that can be done and is being done.